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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/542,546	04/03/2000	Pierre Duhot	31640-159397	4816

7590 12/29/2004

Venable
P.O.Box 34385
Washington, DC 20043-9998

EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/542,546

Applicant(s)

DUHOT ET AL.

Examiner

Elizabeth F. McElwain

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 12, 13, 17, 18, 20, 21, 23 and 30-36 is/are pending in the application.
- 4a) Of the above claim(s) 35 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 12, 13, 17, 18, 20, 21, 23 and 30-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

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The amendment filed September 27, 2004 has been entered.

Claims 1 and 12 are newly amended.

Claims 3-11, 14-16, 19, 22 and 24-29 have been cancelled.

Claims 35 and 36 are newly submitted.

Newly submitted claims 35 and 36 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are drawn to use of a nucleic acid encoding S-adenosyl methionine, which is not a methyl transferase.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 35 and 36 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1, 2, 12, 13, 17, 18, 20, 21, 23 and 30-34 are drawn to the elected invention and are examined in the instant office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejections that have not been repeated have been withdrawn.

Claim 12, and claims 13, 17-18, 20, 21, 30 and 32-34 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 12 is indefinite in that it is unclear if the claimed promoter is limited to a promoter of a methyl transferase gene or if it may be any plant expressible promoter.

Clarification is requested.

Applicants' arguments filed September 27, 2004 have been fully considered but they are not persuasive. Applicants argue that the specification discloses that a variety of promoters may be used. The Examiner maintains that the wording of the claims suggests that the claim is limited to the use of a promoter of a methyl transferase gene. Amendment of the claim to recite that the plant expressible promoter is operably linked to the nucleic acid coding for the methyl transferase would make clear that the claim is not limited use of a methyl transferase promoter.

Claims 1, 2, 12, 13, 17, 18, 20, 21, 23, and 30-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated in the last office action.

Applicant's arguments filed September 27, 2004 have been fully considered but they are not persuasive. Applicants argue that the rejection should be withdrawn given that the functional activity of methyl transferases was well known in the prior art and several types are known that transfer a methyl group to the N-position, the C-position or the S-position, for example. In addition, the specification discloses two methyl transferase genes. Applicants also argue that it was well known at the time of filing that plant cells contain various fatty acids

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necessary for lipid metabolism. Applicants assert that the methyl group is added to the double bond of a fatty acid, and that this is a specific reaction for which two methyl transferases are sufficient to support the whole genus.

The Examiner maintains that a description of two methyl transferases does not adequately describe the entire genus that is claimed, and that applicants have not described the structural features that are common to the genus that has as a common feature catalyzing the transfer of a methyl group to an aliphatic chain of an unsaturated fatty acid. Instead, applicants have pointed out that the family of methyl transferases includes those that can transfer a methyl group to any of the N-position, the C-position or the S-position, for example. So while methyl transferases function in transferring a methyl group, the members of this family differ from one another with regard to the particular molecules they interact with and can transfer the methyl group to. Applicants have not described the genus that will function in catalyzing the transfer of a methyl group to an aliphatic chain of an unsaturated fatty acid.

Claims 1, 2, 12, 13, 17-21, 23 and 30-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth in the scope of enablement rejection in the last office action, wherein the specification, while being enabling for transforming tobacco with a cyclopropane fatty acid synthase gene to produce branched fatty acids in a plant, does not reasonably provide enablement for the production of branched fatty acids in any plant with any gene that encodes an enzyme that will transfer one or more

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alkyl groups to the double bond of an unsaturated fatty acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last office action.

Applicants' arguments filed September 27, 2004 have been fully considered but they are not persuasive. Applicants assert that the rejection should be withdrawn. Applicants argue that all methyl transferases function in the same manner by transferring a methyl group, and that other methyl transferase genes were known in the art. Applicants argue that the articles that the Examiner relied on are not relevant to an enzyme that will transfer a methyl group, and the De Luca reference concerns secondary metabolic pathways, not primary metabolic pathways. Applicants also argue that prophetic examples may be supported by the specification, and thus be enabling.

The Examiner maintains that the disclosure is only enabling for transforming tobacco with a cyclopropane fatty acid synthase gene to produce branched fatty acids in a plant, and does not reasonably provide enablement for the production of branched fatty acids in any plant with any gene that encodes an enzyme that will transfer one or more alkyl groups to the double bond of an unsaturated fatty acid. The Examiner maintains that the cited references establish that without having the genes encoding methyl transferases in hand, and without having transformed a plant with said genes and establishing that branched fatty acids are produced, it cannot be established that branched fatty acids will be produced, particularly given that the methyl transferase is part of a primary metabolic pathway, as applicants have stated,

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previously. While transforming plants with gene constructs is not unpredictable, the effects of the gene construct on a plant is not predictable, given that each plant species differs in biochemical composition with regard to the availability of precursor fatty acids and the feedback mechanisms in each species. The Examiner maintains that the teachings in the specification are only enabling for transformation of tobacco with a cyclopropane fatty acid synthase gene. Therefore, for the reasons stated in the last office action, it would require undue experimentation for one skilled in the art to make and/or use the claimed invention.

No claims are allowed.

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

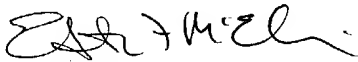
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804.

Please note that the fax phone number for the organization where this application or proceeding is assigned has changed. The new number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Elizabeth F. McElwain, Ph.D.
Primary Examiner
Art Unit 1638

EFM